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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,543	09/05/2000	Dominique P. Bridon	REDC-2200 US	5070

20872 7590 12/16/2004

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EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/623,543	BRIDON ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-48* is/are pending in the application.

4a) Of the above claim(s) *27 and 30-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-26, 28, 29, 33-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *October 12, 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendments and Arguments

Election/Restrictions

1. The election/restrictions requirement mailed September 29, 2003 has been withdrawn to the extent species, SEQ ID NO: 39 will be examined with elected species, SEQ ID NO: 8. SEQ ID NO: 8 has been found free of the art. The remainder of the requirement is deemed FINAL.

2. Claims 22-48 are pending.

Claims 1-21 have been cancelled.

Claims 22-48 have been added.

Claims 27 and 30-32, drawn to a non-elected invention is withdrawn from examination.

Claims 22-26, 28, 29 and 33-48 are examined on the merits to the extent they read on SEQ ID NO: 8 and SEQ ID NO: 39.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objection

Claim Objections

4. The objection of claims 2, 11 and 21 is withdrawn in light of the cancellation of the claims.

Withdrawn Rejections

Claim Rejections - 35 USC § 112

5. The rejection of claims 1-4, 7-10, 13, 14, 17 and 18 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of the cancellation of the claims.

6. The rejection of claims 1-21 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of the cancellation of the claims.

Claim Rejections - 35 USC § 101

7. The rejection of claims 17 and 18 under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101 is withdrawn in light of the cancellation of the claims.

Claim Rejections - 35 USC § 102

8. The rejection of claims 1-5, 7-11, 13-15, 17 and 18 under 35 U.S.C. 102(b) as being anticipated by WO 97/41824 (13 November 1997/ IDS reference AM on sheet 1 of 3, February 2001) is withdrawn in light of the cancellation of the claims.

9. The rejection of claims 1-5, 7-11, 13-15, 17 and 21 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent number 6,057,122 (filed May 5, 1997/ IDS reference AD on sheet 2 of 3, February 2001) is withdrawn in light of the cancellation of the claims.

Double Patenting

10. The provisional rejection of claims 1-16 and 19-21 under 35 U.S.C. 101 as claiming the same invention as that of claims 1-16 and 19-21 of copending Application No. 09/657,431 (filed September 7, 2000) is withdrawn in light of the cancellation of the claims.

11. The provisional obviousness-type double patenting rejection of claims 17 and 18 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 and 19-21 of copending Application No. 09/657,431 (filed September 7, 2000) is withdrawn in light of the cancellation of the claims.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

12. Claims 22-25, 28, 34-38, 41-45 and 48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In anticipation of the instant rejection Applicants aver that extensive written description support for modified anti-angiogenic peptide comprising a region of mammalian plasminogen, and numerous anti-angiogenic peptide species that correspond to a region of mammalian plasminogen is provided in the specification, see Remarks pages 10-13. Applicants pointedly express where in the specification by page and line number where support can be found for "...Applicants... possession of anti-angiogenic peptides corresponding to regions of mammalian plasminogen commensurate with the scope of the claims at the time of filing." Applicants' arguments address each claim in relation to the assertion that they had possession of the said anti-angiogenic peptides, modified kringle 5 peptides and specific kringle 5 peptide sequences. These arguments and points of view have been carefully reviewed and considered, but found unpersuasive.

Applicants continue to broadly claim a method of administering to a patient a modified anti-angiogenic peptide, a kringle 5 peptide, a modified kringle 5

peptide and a conjugate of formula comprising the said peptides for treatment of a subject with angiogenesis. The written description in this instant case only sets forth an antiangiogenic peptide, wherein said peptide is a kringle 5 peptide identified as SEQ ID NO: 8 and 39. The written description is not commensurate in scope with the claims drawn to all the possible combinations of kringle 5 peptides as modified anti-angiogenic peptides.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 115).

With the exception of the defined amino acid residues identified as SEQ ID NO: 8 and 9 the skilled artisan cannot envision the detailed structure of the encompassed polypeptides and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The polypeptide itself is required. See *Fiers v. Revel*, 25 USPQ 2d

1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Furthermore, In *The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

Support for the antiangiogenic kringle 5 peptides, designated as SEQ ID NO: 8 and 39 is provided in the specification. At the time the application was filed Applicants only had possession of the kringle 5 peptides designated as SEQ ID NO: 8 and 39. As the broad claims are written the language indicates that these claims are drawn to an entire genus. The specification does not evidence the possession of all the possible variant peptides, derivatives and fragments of kringle 5 or a modified antiangiogenic peptides that could or could not possibly inhibit angiogenesis, as well as their use in the methods of manufacture and treatment. There is insufficient to support the generic claims as provided by the

Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

The full breadth of the claims does not meet the written description provision of 35 U.S.C. 112, first paragraph.

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 22-26 and 35-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 22 and 35 are vague and indefinite in the recitation "...peptide corresponding to a region of mammalian plasminogen...". It is not clear which amino acid residues are included in this peptide that "corresponds" to mammalian plasminogen. It is not clear what *corresponds* means in the context of the claims. The term, corresponds does not clarify whether or not the peptide is similar to the said plasminogen structurally or functionally. It is not clear if the isolated amino acid sequence corresponding to the said kringles is fragments, variants or the entire amino acid sequence that is the same as the designated mammalian plasminogen. Accordingly, the metes and bounds of the claims cannot be determined.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

16. Claim 33 is rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent number 5,981,484 (filed April 3, 1997). U.S. Patent #5,981,484 discloses SEQ ID NO: 13, the same as Applicants' SEQ ID NO: 39, see column 51. This modified kringle 5 peptide treats angiogenic diseases and are administered to patients, see the Abstract on the first page; column 2, lines 60-63; bridging paragraph of columns 2 and 3.

Double Patenting

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 35-48 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 10 and 11 of copending Application No. 09/657,431 (filed September 7, 2000). Although the conflicting claims are not identical, they are not patentably distinct from each other because the anti-angiogenic kringle 5 peptides identified as SEQ ID NO: 2-16 are the same in both applications. The formulations cited in the both applications intrinsically would retain the same properties.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**.

See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571) 272-0831. The examiner works a flexible schedule, however she can normally be reached between the hours of 6:30 am to 5:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

Alana M. Harris, Ph.D.
13 December 2004